4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4076]

Benefit-Risk Assessments in Drug Regulatory Decision-Making; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public meeting to convene a discussion of topics related to the structured assessment of benefits and risks in drug regulatory decision-making. This meeting will focus on regulatory and industry experiences with approaches to structured benefit-risk assessments, approaches to incorporating patient perspectives into structured benefit-risk assessment, and exploration of methods to advance structured benefit-risk assessment. The format of the meeting will include a series of presentations on the above topics related to structured assessment of benefits and risks, followed by a discussion on those topics with invited panelists and audience members. This meeting satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

DATES: The public meeting will be held on September 18, 2017, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by September 11, 2017 (see the SUPPLEMENTARY INFORMATION section for instructions). Public comments will be accepted through November 18, 2017. See the ADDRESSES section for information about submitting comments to the public docket.

ADDRESSES: The public meeting will be held on September 18, 2017, at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center (the Great Room) , Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 18, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of November 18, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-4076 for "Benefit-Risk Assessments in Drug Regulatory Decision-Making; Public Meeting, Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that

states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at: https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm378861.htm

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1146,

Silver Spring, MD 20993-0002, 301-796-5003, FAX: 301-847-8443,
graham.thompson@fda.hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144). Title I of FDASIA reauthorizes PDUFA V and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA V includes performance goals and procedures for the Agency that represents FDA's commitments during fiscal years 2013-2017. These commitments are fully described in the document entitled "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017" (PDUFA Goals Letter), available on FDA's website at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.

Section X of the PDUFA Goals Letter, entitled "Enhancing Benefit-Risk Assessment in Regulatory Decision-Making," includes development of a plan to further develop and implement a structured approach to benefit-risk assessment in the human drug review process. As part of this enhancement, FDA committed to holding two public workshops on benefit-risk considerations from the regulator's perspective that will begin by the first quarter of fiscal year 2014. The public workshop held in 2014 fulfilled the first of the two workshop commitments. The workshop announced by this notice will fulfill the second of the two workshop commitments.

As part of its commitment, FDA has published the "Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making: Draft PDUFA V Implementation Plan," available on FDA's website at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf. In this Plan, FDA identified as an area of further development the exploration of structured approaches to evaluate and communicate the assessment of benefits and risks. FDA's human drug regulatory decisions are informed by an extensive body of evidence on the safety and efficacy of a drug product, as well as other factors affecting the benefit-risk assessment, including the nature and severity of the condition the drug is intended to treat or prevent, the benefits and risks of other available therapies for the condition, and any risk management tools that might be necessary to ensure that the benefits outweigh the risks. A structured benefit-risk framework serves as a foundational element to FDA's benefit-risk assessments.

II. Purpose and Scope of the Meeting

This public meeting will focus on: (1) regulatory and industry experiences with approaches to structured benefit-risk assessments, and the results of implementing structured frameworks at regulatory agencies both for premarket application review and postmarket safety review, (2) approaches to incorporating patient perspectives into structured benefit-risk assessment, and (3) exploration of methods to advance structured benefit-risk assessment. This meeting will be an opportunity to share any challenges and lessons learned in applying a more structured approach to regulatory decision-making. The public meeting will also explore more systematic and structured approaches to evaluate and communicate methods of assessing benefits and risks; and their implications on human drug regulatory decisions. Specifically, the workshop will examine FDA, other regulatory agencies, industry, and external perspectives and

experiences with structured benefit-risk assessment. This public meeting will have discussion sessions focusing on the entire drug development life cycle, including premarket drug review and postmarket safety surveillance. The format of the meeting consists of a series of presentations on topics related to structured assessment of benefits and risks, followed by a discussion on those topics with invited panelists and audience members.

III. Meeting Attendance and Participation

Registration: If you wish to attend this meeting, visit https://fdabenefitrisk.eventbrite.com. Please register by September 11, 2017. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Seating will be limited, so early registration is recommended.

Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations because of a disability, please contact Graham Thompson (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm378861.htm.

Dated: August 3, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-16720 Filed: 8/8/2017 8:45 am; Publication Date: 8/9/2017]